PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Lixiao Wang
Application No.:	08/685338
Filed:	July 23, 1996
For:	High Compliance, High Strength Catheter Balloons Useful for Treatment of Gastrointestinal Lesions
Examiner:	Cris Loiren Rodriguez
Group Art Unit:	3763

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.:
S63.2B-5902-US01

DECLARATION OF GREG MITCHELL

Greg Mitchell states:

1. I am a Manufacturing Engineer at Boston Scientific Corporation's Maple Grove Minnesota facility. My responsibilities include transferring new products into production and maintaining production of existing products, the latter including Boston Scientific Corporation's C•R•E™ catheters. I am familiar with and am responsible for maintaining the manufacturing processes for the balloons C•R•E™ balloons.

2. Accompanying this Declaration is a document entitled Supplement to Greg Mitchell Declaration that contains confidential business information of Boston Scientific Corporation that is exempt from FOIA Disclosure, (FOIA exemption 4 (5 U.S.C. 552(b)(4)). On that document is a more detailed description of the process described herein and certain process parameters used in that process.

3. The C•R•E™ balloons are formed of block copolymer material. They are each sized to display three distinctively different diameters at predetermined inflation pressure intervals, a low pressure at 3 atm inflation pressure, an intermediate pressure where the size is 1 or 1.5 mm larger and a higher pressure where the size is again 1 or 1.5 mm larger. That is, within a specified useful range (reliably below burst pressure) there is a target growth of 2-3 mm. Six sizes are

marketed, 6/7/8 mm; 8/9/10 mm; 10/11/12 mm; 12/13.5/15 mm; 15/16.5/18 mm; and 18/19/20 mm, where the slashes separate the respective low, intermediate and high pressure diameters.

4. Of the six sizes, the first five use a pre-sterilization shrinking step. This is a costly extra step in the manufacturing step. The company is actively trying to qualify an alternative manufacturing method based on more recent technology. However, from the introduction of the C•R•E™ balloon line to the present date, the only balloon in the line that has met the minimum 2 mm growth target for this line, without using a pre-sterilization shrinking step, has been the very largest balloons, namely the 18/19/20 balloons. The other balloons in the line are not sufficiently compliant in the useful pressure range if the shrinking step is avoided. This is verified by a comparative experiment that I have recently performed.

5. In recent production runs of the 6/7/8 mm and 15/16.5/18 mm balloons, I isolated fifteen balloons of each size for comparative testing. Of the fifteen balloons, five were prepared exactly according to the production protocol, up to the point where they were ready for mounting and sterilization. The balloons ("Invention") were then set aside for balloon testing. I am informed that the claims of the above application recite a pre-sterilized balloon that has been subjected to a shrinking step after it was formed. The data for the Invention balloons therefore are representative of the invention, the balloon having been shrunk after blowing but still in its pre-sterilized condition.

6. Five balloons were formed the same way, but the balloons ("Production") were then taken through the standard company sterilization protocol to show the final production profile obtained by the balloons of the invention.

7. Finally, a group of five balloons ("Control") was also formed in which the balloon shrinking step was omitted. The Control balloons were taken through the same company standard sterilization protocol as the Production balloons.

8. All of the test balloons were then mounted on a test fixture and sequentially pressurized to the low and high dilation pressures designated for the production balloons. Average balloon diameters for these balloon sets is reported in the table for each set of five balloons, with the first diameter number taken at the specified low pressure for the commercial balloon and the second taken at the specified high pressure for the commercial balloon.

Size \ Description	Measured Diameter		
	Control (no shrink sterilized)	Invention (shrunk, pre-sterilized)	Production (shrunk and sterilized)
6/7/8 mm	6.12/8.04	6.06/7.98	5.84/8.01
15/16.5/18 mm	15.76/18.10	15.45/18.03	15.20/18.04

9. The table data demonstrates that the Invention balloons are distinguished from the Control balloons by their smaller low pressure diameter. After the Invention balloons have been sterilized, the initial balloon diameter drops further, so the resulting production balloons are much more compliant over the inflation pressure range than the control balloons.

10. The C•R•E™ balloon catheters were introduced in 1998. I am not aware of any way that the first five C•R•E™ balloon size combination products could have been made at that time, other than by using the pre-sterilization shrinking step. In particular, I have reviewed the patents of Hamilton et al. (US 5,797,877), and Anderson et al. (US 5,500,180). I did not find anything in those documents that appears to teach or suggest performing a pre-sterilization shrinking step on a block copolymer balloon. In my opinion, any balloon described in those patents, whether looked at in pre-sterilized or post-sterilized condition, will not have a compliance profile that is the same as the compliance profile that would be obtained if the same balloons had been subjected to a pre-sterilization shrinking step.

11. The undersigned being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

States Code and that such willful false statements may jeopardize the validity of the application or any resulting registration, declares all statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

11/3/04
Date

Greg Mitchell